UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NELSON GALLEGO, as Administrator of the Estate of JILLIAN ROSE CASTRO FIGUEROA,

Plaintiff,

v.

TANDEM DIABETES CARE, INC.,

Defendant.

MEMORANDUM & ORDER
24-CV-146 (MKB)

MARGO K. BRODIE, United States District Judge:

Plaintiff Nelson Gallego, as administrator of the estate of Jillian Rose Castro Figueroa ("Decedent"), commenced the above-captioned action against Defendant Tandem Diabetes Care, Inc. and filed an Amended Complaint asserting claims arising out of Decedent's use of Defendant's model t:slim X2 insulin pump ("X2 Pump").[1] (*See* Compl., annexed to Notice of Removal as Ex. A, Docket Entry No. 1-1; Am. Compl., Docket Entry No. 15.) On March 28, 2025, the Court granted Defendant's motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure on preemption grounds and for failure to state a claim and dismissed the Amended Complaint (the "March 2025 Decision"). *Gallego v. Tandem Diabetes Care, Inc.*, --- F Supp. 3d ---, ---, 2025 WL 948292, at *1 (E.D.N.Y. Mar. 28, 2025). The Court dismissed without prejudice Plaintiff's negligent defective design and wrongful death claims[2] and granted

[1] On December 13, 2023, Plaintiff commenced this action in the Supreme Court of the State of New York, Queens County, and on January 8, 2024, Defendant removed the case to the Eastern District of New York. (Notice of Removal ¶ 1, Docket Entry No. 1.)

[2] The Court dismissed with prejudice Plaintiff's claims for strict products liability based on manufacturing defect, negligence, strict products liability based on failure to warn, and breach of

Plaintiff thirty days to replead the two claims in a second amended complaint.

On April 25, 2025, Plaintiff moved for "pre-answer discovery" of certain documents, records, and materials in Defendant's possession and for an extension of Plaintiff's deadline to file a second amended complaint to sixty days from his receipt of the requested discovery materials. (Letter Mot. for Disclosure, Mot. for Extension of Time to Amend Complaint ("Pl.'s Mot."), Docket Entry No. 31.) Defendant opposes Plaintiff's motion and requests that the Court order Plaintiff to file a second amended complaint within seven days of denying Plaintiff's motions. (Letter Response to Pl.'s Mot. ("Def.'s Opp'n"), Docket Entry No. 32.) For the reasons stated below, the Court denies Plaintiff's motion for discovery and directs Plaintiff to file a second amended complaint within fourteen days of this Memorandum and Order.

I. Background

The Court assumes familiarity with the March 2025 Decision and briefly summarizes the Court's findings as to Plaintiff's negligent defective design claim. Construing the Amended Complaint liberally, the Court found that Plaintiff alleged that Decedent's X2 Pump was defective in that the device could not withstand droppage, that the defect was due to Defendant deviating from requirements that were "set by the [Federal Drug Administration ("FDA")] as part of the pre-approval process," including by not "appropriately screen[ing] the device for certain failure modes, including droppage," and that the defect caused the Decedent's death in that the X2 Pump, which showed signs of being dropped, stopped delivering insulin. *Gallego*, 2025 WL 948292, at *11 & n.13 (quoting Am. Compl. ¶¶ 17–18, 66). For these allegations to survive preemption, Plaintiff also had to sufficiently plead, or allege facts from which the Court could infer, that the

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implied warranty of merchantability on preemption grounds and Plaintiff's wrongful death claim to the extent based on these preempted claims for failure to state a claim. *Gallego v. Tandem Diabetes Care, Inc.*, --- F Supp. 3d ---, ---, 2025 WL 948292, at *16 (E.D.N.Y. Mar. 28, 2025).

requirements "set by the FDA as part of the pre-approval process" governed screenings for failure modes that Defendant was required to conduct after receiving pre-market approval ("PMA") for the X2 Pump. *Id.* at *11. Plaintiff neither alleged a specific requirement that Defendant had violated nor alleged facts from which the Court could reasonably infer Defendant committed such a violation. *Id.* at *11–12. Plaintiff also alleged that "the [X2 Pump] could have been designed in such a way as to decrease the likelihood of mechanical failure or failure as a result of the pump being dropped, such as . . . by complying with failure modes set by the FDA as part of the pre-approval process." *Id.* at 12 (quoting Am. Compl. ¶ 18). Based on these allegations and the absence of a basis from which to infer a post-PMA violation, the Court found that Plaintiff's negligent defective design claim amounted to a challenge of FDA's approved design or its pre-approval process, entitling Defendant to the defense of preemption on the face of the Amended Complaint. *Id.* at 12. The Court granted Plaintiff leave to replead his negligent defective design claim premised on failure to comply with design failure modes and his wrongful death claim to the extent it is premised on the repleaded negligent defective design claim.[3] *Id.* at 15.

Plaintiff now seeks a court order directing Defendant to turn over the following documents and records in Defendant's possession:

- Risk Management policy, terms, definitions, processes, explanation of risk assessment processes, and recognized Risk Management standards followed by Defendant;
- Failure Modes and Effects Analysis (FMEA) (or similar process) for t:slim X2 pump including portions dealing with failure mode from damage due to drops;
- FMEA policy, FMEA processes, FMEA terms, FMEA definitions;
- Hazard Analysis (HA) (or similar process) for t:slim X2 pump, including portions dealing with Hazards potentially leading to serious injury or death;
- HA policy; HA processes; HA terms; HA definitions; and specific procedures dealing with Hazards identified as possibly leading to "death";
- All t:slim X2 pump complaint reports mentioning ERROR 20 as outlined in the user guide;

[3] The Court dismissed with prejudice Plaintiff's negligent defective design claim premised on other alleged theories. *Gallego*, 2025 WL 948292, at *11–12.

- All t:slim X2 pump documentation about to ERROR 20 as outlined in the user guide;
- All t:slim X2 pump documentation relating to drop testing;
- All t:slim X2 pump repairs AND complaints where "drive train" is mentioned;
- All t:slim X2 pump documentation relating to User Guide portions: 2.2 t:slim X2 Insulin Pump Precautions, 2.6 Verification of Proper Functionality, and 13.4 Cartridge Error Alarm;
- All t:slim X2 pump documentation relating to process' followed in Device Investigation followed by Customer Technical Support (CTS) on Page 7 of 6/13/2022 Tandem report;
- All t:slim X2 pump documentation relating to process followed in Device Investigation followed in "Device Investigation" of 6/13/2022 Tandem report; and
- Complete design and specification file for the t:slim X2 pump, inclusive of any associated manufacturer certifications.

(Pl.'s Mot. 1–2.) Defendant opposes Plaintiff's request. (Def.'s Mot. 1.)

II. Discussion

Plaintiff argues that the requested discovery is necessary for him to plead a negligent defective design claim "with the requisite specificity." (Pl.'s Mot. 1.) He also contends that his request stems from "inconsistencies between the investigation report provided by [Defendant] and the user guide for the subject pump" and "necessary information that is not included in the [Defendant's] report regarding the subject device." (*Id.* at 1–2.)

Defendant argues that "the Court should require some specificity in pleading through a second amended complaint before allowing any discovery" as other courts "addressing similar requests" have done and that "[t]hough [c]ourts recognize the challenge of pleading a parallel claim prior to discovery, when (as is the case here) a plaintiff fails 'to adequately plead that defendant violated a federal requirement specific to the FDA's PMA approval,' discovery should be disallowed." (Def.'s Opp'n. 1.) Defendant also argues that the Court should deny Plaintiff's request because (1) "Plaintiff apparently concedes that he has no facts to replead his negligent design claim and the Court should not open the doors to discovery"; (2) Plaintiff does not need pre-answer discovery to meet the pleading standard because "post-approval requirements for the [X2 Pump] are contained within the PMA approval order, which, along with the PMA

supplements and medical device reports, are publicly available from FDA"; (3) "Plaintiff does not request information that is in anyway tailored to pinpointing a federal requirement for post-approval design failure mode screenings" and instead "requests broad discovery on policies and analyses relevant to the premarket approval process"; and (4) "Plaintiff should not be permitted discovery into Defendant's investigation of Plaintiff's device" as "[e]vents and investigation occurring after Plaintiff's alleged injuries will not expose what the Court instructed Plaintiff to plead — a federal requirement[ ] for post-approval design failure mode screenings that [the] FDA imposed on the X2 Pump in the PMA documents." (*Id.* at 1–2.)

"As the Supreme Court has emphasized, a plaintiff must allege facts supporting a plausible claim *before* being entitled to discovery . . . ." *Melendez v. Sirius XM Radio, Inc.*, 50 F.4th 294, 307 (2d Cir. 2022) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009)); *Egbujo v. Jackson Lewis P.C.*, No. 22-2854, 2023 WL 8295317, at *5 (2d Cir. Dec. 1, 2023) (quoting same); *see Ashcroft*, 556 U.S. at 686 (holding that where the complaint fails to adequately plead a claim, the plaintiff "is not entitled to discovery, cabined or otherwise"); *Main St. Legal Servs., Inc. v. Nat'l Sec. Council*, 811 F.3d 542, 567 (2d Cir. 2016) ("A plaintiff who has failed adequately to state a claim is not entitled to discovery." (first citing *Ashcroft*, 556 U.S. at 686; and then citing *Neitzke v. Williams*, 490 U.S. 319, 326–27 (1989))); *Carter v. New York*, 316 F. Supp. 3d 660, 671 (S.D.N.Y. 2018) (same). "[D]iscovery is authorized solely for parties to develop the facts in a lawsuit in which a plaintiff has stated a legally cognizable claim, not in order to permit a plaintiff to find out whether he has such a claim, and still less to salvage a lawsuit that has already been dismissed for failure to state a claim." *Main St. Legal Servs.*, 811 F.3d at 567–68 (alteration in original) (quoting *Podany v. Robertson Stephens, Inc.*, 350 F. Supp. 2d 375, 378 (S.D.N.Y. 2004)); *K.A. v. City of New York*, No. 16-CV-4936, 2021 WL 5889254, at *2 (S.D.N.Y. Dec. 13, 2021) (noting that the

"Federal Rules of Civil Procedure require [p]laintiffs to state a claim upon which relief may be granted without access to information that is in [d]efendants' sole control" and collecting cases denying discovery requests that were "lodged for the purpose of obtaining extra information prior to amending a complaint"). "[A] district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *In Touch Concepts, Inc. v. Cellco P'ship*, 788 F.3d 98, 102 (2d Cir. 2015) (alteration in original) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007)); *Lynch v. City of New York*, 952 F.3d 67, 75 (2d Cir. 2020) ("The assessment of whether a complaint's factual allegations plausibly give rise to an entitlement to relief' . . . simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal conduct." (first quoting *Twombly*, 550 U.S. at 556; and then citing *Iqbal*, 556 U.S. at 678)).

Plaintiff has not yet pleaded a plausible claim for relief and is therefore not entitled to discovery. Nor has Plaintiff offered any legal authority to compel discovery for the purpose of aiding him in amending a complaint or clarifying information in publicly available documents. *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 673 (S.D.N.Y. 2017) (denying plaintiff's discovery requests because "they are not entitled to discovery on preempted claims" and the "motion to dismiss mechanism exists to prevent plaintiffs from conducting fishing expeditions to see if they can cobble together meritorious claims"), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). Although Plaintiff contends that he is "unable to fully articulate" a claim without access to the documents in Defendant's possession, (Pl.'s Mot. 1), this is no basis to circumvent the requirement that he state a claim before proceeding to discovery. *See, e.g.*, *K.A.*, 2021 WL 5889254, at *2 (denying request for early discovery intended to "place [plaintiffs] in a more equal position of information to the [d]efendants and to

better [enable them] to file a [s]econd [a]mended [c]omplaint" because "plaintiff's desire to gain more information in order to generate stronger pleadings is not a legitimate basis to compel discovery at this early stage in the litigation" (third alteration in the original)); *see also Yamashita v. Scholastic Inc.*, 936 F.3d 98, 106–07 (2d Cir. 2019) (affirming dismissal where plaintiff failed to "marshal more than unsubstantiated suspicions to gain entitlement to broad-ranging discovery" but with "some sympathy" as "[plaintiff] had no access . . . to information" in defendant's possession that would have confirmed or rebutted plaintiff's allegations).

Moreover, even if Plaintiff's discovery request was proper, the Court is not convinced that ordering Defendant to provide such a broad list of materials would comply with the Federal Rules of Civil Procedure's mandate that discovery be "relevant to any party's claim or defense and proportional to the needs of the case," *In re Catalyst Managerial Servs., DMCC*, 680 F. App'x 37, 40 (2d Cir. 2017) (emphasis omitted) (quoting Fed. R. Civ. P. 26(b(1)), or would lead to the "specificity" that Plaintiff seeks, (Pl.'s Mot. 1). Plaintiff mentions "inconsistencies between the investigation report provided by [Defendant] and the user guide for the subject pump" as a basis for his request but does not specify the inconsistencies, (*id.* at 2), or offer any detail for the Court to assess whether the requested list of materials might resolve the inconsistencies. Similarly, Plaintiff points to the need for "necessary information that is not included in the [Defendant's] report regarding the subject device" but does not specify the omitted information or any basis for the Court to conclude that the documents contain the omitted information or would provide the detail Plaintiff believes is necessary for him to plead a parallel claim. (*Id.* at 2.) *See Faison v. Van Zandt*, 141 F.3d 1151, 1151 (2d Cir. 1998) (finding district court's error, if any, in refusing to consider plaintiff's objection that "further discovery" was "necessary information to make out his case" was harmless because "it would put the cart before the horse to suggest that plaintiff's

fishing expedition would have helped him make out a complaint").

Accordingly, the Court denies Plaintiff's request for discovery. The Court grants Plaintiff fourteen days to replead his negligent defective design and wrongful death claims in a second amended complaint.[4]

III. Conclusion

For the foregoing reasons, the Court denies Plaintiff's motion for pre-Answer discovery and grants Plaintiff's motion for an extension of time. The Court grants Plaintiff fourteen days from the date of this Memorandum and Order to replead the negligent defective design and wrongful death claims in a second amended complaint. If Plaintiff fails to timely file a second amended complaint, the Court will direct the Clerk of Court to enter judgment for Defendant and close this case.

Dated: May 31, 2025
Brooklyn, New York

SO ORDERED:

/s/MKB
MARGO K. BRODIE
United States District Judge

[4] Plaintiff contends that he needs the requested discovery to plead his claim "with the requisite specificity," (Pl.'s Mot. 1), and Defendant argues that "the Court instructed Plaintiff to plead . . . a federal requirement[ ] for post-approval design failure mode screenings that FDA imposed on the X2 Pump in the PMA documents," (Def.'s Opp'n 2.) For clarity, the Court notes that to survive preemption, the second amended complaint would need to plead a specific PMA requirement Defendant violated ***or*** allege facts sufficient for the Court to reasonably infer, when taking the allegations as true and in a light most favorable to Plaintiff, that such a violation did occur. *See Gallego*, 2025 WL 948292, at *11–12; *id.* at 12 ("'[I]in the context of a motion to dismiss,' the factual allegations relevant to a preemption argument 'must be viewed in the light most favorable to the plaintiff' and a 'district court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not preempted'" (quoting *Galper v. JP Morgan Chase Bank, N.A.*, 802 F.3d 437, 444 (2d Cir. 2015))).